### **REMARKS**

This is a full and timely response to the Office Action mailed January 22, 2004.

By this Amendment, the specification has been amended to (1) make the title more descriptive of the claimed subject matter, (2) add a specific reference to the provisional application (i.e. provisional application 60/256,948 filed December 21, 2000) upon which domestic priority is based, and (3) replace the Sequence Listing of record with a substitute sequence listing in compliance with the Sequence Rules under 37 C.F.R. §§1.821-1.825.

Claim 1 has been amended. Support for claim amendments can be found throughout the specification. Claims 1-17 are pending in this application, with claims 2-17 being withdrawn. In view of these amendments, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

# Claim of Priority Under 35 U.S.C. §119(e)

Applicant has amended the specification to add a specific reference to provisional application 60/256,948 filed December 21, 2000 as per the Examiner's request.

# Objection to the Title of the Invention

Applicant has amended the Title to make it more descriptive of the claimed subject matter. Thus, withdrawal of this objection is requested.

### **Sequence Listing**

Applicant has submitted herewith a paper copy of a substitute Sequence Listing for the above-identified application which has been prepared in accordance with the sequence rules under 37 CFR §§1.821-1.825. The substitute Sequence Listing contains the identical sequences appearing in the original Sequence Listing and application papers. Thus, no new matter has been added.

There is also submitted herewith a copy of the Sequence Listing in computer readable form as required by 37 CFR 1.821(c). The content of the paper and computer readable copies are the same.

Entry of the substitute Sequence Listing has also been requested in the amendments above.

Thus, Applicant believes that the application is now in compliance with the sequence rules under 37 CFR 1.821-1.825.

# Rejections under 35 U.S.C. §112

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, for alleged indefiniteness. Applicant respectfully traverses this rejection.

Claim 1 is directed to "a western equine encephalitis virus strain comprising the nucleotide sequence shown in SEQ ID NO: 1". In other words, the claimed invention is directed to a particular strain of the western equine encephalitis virus as defined by a specific nucleotide sequence or genetic constitution. None of the words or phrases in claim 1 is ambiguous or indefinite since they are well understood by one skilled in the art.

The argument put forth by the Examiner that claim 1 is indefinite for recitation of the transitional term "comprising" which is open language and which results in the intended metes and bounds of the other elements beside SEQ ID NO: 1 not being defined, is an argument which can apply to all claims using such a transitional term.

The fact that the term "comprising" is open language and does not exclude additional, unrecited elements or method steps does not by itself renders the claim indefinite. In fact, because the term "comprising" is such a well understood term of art, it cannot be argued that the term is ambiguous or indefinite. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS*, *Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

35 U.S.C. §112, second paragraph, requires that the claims must set forth the subject matter that applicants regard as their invention, and must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. Here, in this case, claim 1 does particularly point out and distinctly define the metes and bounds

of the claimed subject matter. In its broadest reasonable interpretation, claim 1 encompasses all western equine encephalitis viruses comprising the nucleotide sequence shown in SEQ ID NO:

1. Since particular strains of viruses (see pages 22-25 of the specification) are typically distinguished by genotype, a claim defining a particular strain of a western equine encephalitis virus by a nucleotide sequence is not vague or indefinite.

It should be noted that the Examiner might be rejecting claim 1 as indefinite due to its breadth. However, breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

Thus, for these reasons, withdrawal of this rejection is respectfully requested.

### Rejections under 35 U.S.C. §103

Claim 1 is rejected under 35 U.S.C. §103(a) as being allegedly obvious over Hahn et al. (PNAS, 1988, Vol. 85, pages 5997-6001). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the cited reference must teach or suggest all the claim limitations (see §2143 of the Manual of Patent Examining Procedure). Here, in this case, Hahn et al. fails to teach or suggest "the nucleotide sequence shown in SEQ ID NO: 1".

Hahn et al. sequenced the 26S region of a different strain (BFS1703) of the western equine encephalitis virus (see page 6, lines 12-18, of the specification). This strain BFS1703 of the western equine encephalitis virus does not comprise the claimed "nucleotide sequence of SEQ ID NO: 1."

As stated on page 20, lines 21-23, of the specification, "[C]omparison of the structural region of WEE 71V-1658 with WEE BFS 1703 (Hahn et al., 1988), indicated 53 nt changes, resulting in only 11 amino acid differences, of which two were nonconserved."

Also, page 23, lines 3-9, "[C]omparison of WEE 71V-1658 to other partial sequences of WEE (Hahn et al., 1988; Weaver et al., 1993) suggests little variation at the nucleotide level among these viruses (Table 2), showing an overall nt sequence difference of 1.7% over 8624 nt. Given a calculated rate of divergence of 0.028% per year for the WEE El protein (Weaver et al., 1997), the expected nt divergence for a difference in isolation of 18 years

between the strains, should be 0.5% (71V-1658 isolated in 1971 and BFS 1703 in 1953). The E1 protein itself showed a rate of divergence of 1.5% in nt sequence between 71V-1658 and BFS1703".

Further support of the distinctions between the nucleotide sequences in western equine encephalitis virus strains 71V-1658 and BFS1703 can be found in Table 2 of the specification.

Thus, since it is clear from the teachings in the specification and Hahn et al, that Hahn et al. fails to teach or suggest the claimed "nucleotide sequence of SEQ ID NO: 1", this rejection can not be sustained and should be withdrawn.

#### CONCLUSION

For the foregoing reasons, all of the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: April 22, 2004

Respectfully submitted,

Lee Cheng

Registration No.: 40,949

RADER, FISHMAN & GRAUER PLLC 1233 20th Street, N.W. Suite 501 Washington, DC 20036 (202) 955-3750

Attorneys for Applicant

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 180013 for any such fees; and applicant(s) hereby petition for any needed extension of time.